

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
November 24, 2015

**DRAFT MEETING ROSTER**

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**ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)**

**Philip A. Bautista, PharmD**

Division of Advisory Committee and Consultant Management  
Office of Executive Programs, CDER, FDA

**PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEMBERS (Voting)**

**G. Caleb Alexander, MD, MS**

*(Chairperson)*

Associate Professor of Epidemiology and Medicine  
Johns Hopkins School of Public Health  
Center for Drug Safety and Effectiveness  
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Department of Neurology – Stoke Program  
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*(Consumer Representative)*  
Drug Information Consultant/ Medical Writer  
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Division of Geriatric Psychiatry and Neuropsychiatry  
Department of Psychiatry and Behavioral Sciences  
The Johns Hopkins University School of Medicine  
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**Bruce I. Ovbiagele, MD, MSc, MAS**

Professor and Chairman of Neurology  
Medical University of South Carolina  
Charleston, South Carolina

**Justin A. Zivin, MD**

Professor Emeritus  
Department of Neurosciences  
Rancho Santa Fe, California

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**DRAFT MEETING ROSTER (cont.)**

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**TEMPORARY MEMBERS (Voting)**

**Christopher Cassidy**  
(Patient Representative)  
Annandale, Virginia

**Michelle M. Estrella, MD, MHS**  
Attending Nephrologist  
Bayview Medical Center and Johns Hopkins  
Hospital  
Associate Faculty member at the Welch Center for  
Prevention, Epidemiology, and Clinical Research  
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**A. Reghan Foley, MD**  
Staff Clinician  
Neuromuscular and Neurogenetic Disorders of  
Childhood Section, Neurogenetics Branch  
Division of Intramural Research  
National Institute of Neurological Disorders of  
Stroke (NINDS)  
National Institutes of Health (NIH)  
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**Mark W. Green, MD, FAAN**  
Professor of Neurology, Anesthesiology, and  
Rehabilitation Medicine  
Director of Headache and Pain Medicine  
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**Cheri Gunvalson, RN, MS**  
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Clinical Assistant Professor  
University of North Dakota, College of Nursing  
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Chief  
Section on Protein Function in Disease  
Laboratory of Biochemistry  
National Heart, Lung, and Blood Institute, NIH  
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**Aaron S. Kesselheim, MD, JD, MPH**  
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Harvard Medical School  
Director, Program on Regulation, Therapeutics, and  
Law (PORTAL)  
Division of Pharmacoepidemiology and  
Pharmacoeconomics  
Brigham & Women's Hospital  
Boston, Massachusetts

**Glen Nuckolls, PhD**  
Program Director and Executive Secretary  
Interagency Muscular Dystrophy Coordinating  
Committee, Neurogenetics Cluster  
Division of Extramural Research  
NINDS, NIH  
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**Paul Romitti, PhD**  
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Iowa City, Iowa

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**DRAFT MEETING ROSTER (cont.)**

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**ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)**

**Mark Gordon, MD**

*(Acting Industry Representative)*

Director, Clinical Development and Medical Affairs  
General Medicine/Central Nervous Systems  
Boehringer Ingelheim Pharmaceuticals  
Ridgefield, Connecticut

**FDA PARTICIPANTS (Non-Voting)**

**Ellis Unger, MD**

Director  
Office of Drug Evaluation I (ODE I)  
Office of New Drugs (OND), CDER, FDA

**Billy Dunn, MD**

Director  
Division of Neurology Products (DNP)  
ODE I, OND, CDER, FDA

**Ronald Farkas, MD, PhD**

Clinical Team Leader  
DNP, ODE I, OND, CDER, FDA

**Robert Temple, MD**

Deputy Director  
ODE I, OND, CDER, FDA

**Eric Bastings, MD**

Deputy Director  
DNP, ODE I, OND, CDER, FDA